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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,725	10/19/2004	Toshiro Omori	042872	2520

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EXAMINER	
CLARK, AMY LYNN	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,725	OMORI ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *8-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/19/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Claims 1-7 in the reply filed on 12 May 2006 is acknowledged.

Claims 8-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12 May 2006.

Currently, Claims 8-26 are pending.

Claims 1-7 are under examination.

Information Disclosure Statement

The information disclosure statement (IDS) was submitted on 19 October 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claims 1-7 are rendered uncertain by the phrase "A composition having an activity of inhibiting the onset of alcoholic hepatopathy and an activity of healing it, the composition comprising an unadsorbed fraction which is formed by subjecting a barley shochu stillage byproduced in the production of shochu from a barley as a raw material to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbent, in which the unadsorbed fraction contains plural peptides having an average chain length of from 3.0 to 5.0, and these peptides comprise from 24 to 38% of glutamic acid, from 4 to 20% of glycine, from 5 to 10% of aspartic acid, from 4 to 9% of proline and from 4 to 8% of serine in terms of an amino acid composition ratio when the total content of amino acids derived from the peptides is defined as 100%", in Claim 1, because the phrase "an activity of inhibiting the onset of alcoholic hepatopathy and an activity of healing it" is poorly worded and is ambiguous and it is difficult to tell what Applicant is trying to claim. It appears that Applicant is saying that the composition is used to reduce the risk of and/or treat the onset of alcoholic hepatopathy, if this is the case, the claim should be reworded to reflect this. The phrase "the composition comprising an unadsorbed fraction which is formed by subjecting a barley shochu stillage byproduced in the production of shochu from a barley as a raw material to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbent" is also unclear. Applicant appears to be claiming a liquid fraction obtained from filtration of barley lees from fermentation of barley.

The entire claim is poorly worded and so unclear that the claim **must** be corrected to provide a clear and concise description of the Invention Applicant is actually claiming. Furthermore, the metes and bounds of Claim 1 are rendered uncertain by the phrase "unadsorbed fraction", in line 3 and "in which the unadsorbed fraction contains plural peptides having an average chain length of from 3.0 to 5.0 and these peptides comprise from 24 to 35% of glutamic acid, from 4 to 20% of glycine, from 5 to 10% of aspartic acid, from 4 to 9% of proline and from 4 to 8% of serine in terms of an amino acid composition ratio when the total content of amino acids derived from the peptides is defined as 100%" because the phrase "unadsorbed fraction" is not properly defined in either the specification or in the claims and the phrase "plural peptides having an average chain length of from 3.0 to 5.0" does not have a unit of measurement, so "an average chain length of from 3.0 to 5.0" is not clearly defined, furthermore the amounts of the ingredients are not set forth in terms of either 'by weight" or "by volume" amount of the total composition. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claims 1-7 are uncertain because it is unclear as to the identification of the ingredients to which Applicant intends to direct the subject matter. Although the use of common names or traditional/ethanopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical as

noted in this application. The common name or traditional/ethanopharmacological name may have several different Latin names referring to various genus-species of the plant and it is unclear as to which genus and species Applicant is referring. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. Applicant may overcome the rejection by placing the genus-species name of "barley" in parentheses after the term "barley".

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Omori et al. (N, Translation provided herein).

Omori teaches a composition having a fatty liver suppressing activity fractionated from residual liquid of barley *shochu* liquor distillation comprising of an unadsorbed fraction obtained by subjecting barley *shochu* stillage by-produced in the production of barley *shochu* to solid-liquid separation and filtering the material to provide a liquid fraction (See abstract and paragraph 0014 on page 5), please note that the liquid fraction reads on a composition. Omori does not expressly teach an unadsorbed fraction formed by subjecting barley *shochu* stillage to solid-liquid filtration, wherein the unadsorbed fraction contains peptides with an average chain length of 3 to 5 and wherein the peptides comprise 24 to 38% glutamic acid, 4 to 20% glycine, 5 to 10% aspartic acid, 4 to 9% proline and 4 to 8% serine, nor does Omori teach that the total content of amino acids derived from the peptides is from 8 to 14% by weight, nor does Omori teach that the fraction further contains free amino acids, free saccharides, polysaccharides and organic acids nor does Omori teach the fraction contains from 4 to 12% by weight of the free amino acids, from 5 to 10% by weight of the free saccharides, from 15 to 25% by weight of the polysaccharides and from 2 to 8% by weight of the organic acids. However, the composition and fraction, as taught by Omori, is obtained in the same way and produced in the same manner as the composition and fraction claimed by Applicant and is one and the same as the composition and fraction claimed by Applicant. Therefore, the peptide length, amount of amino acids in the peptides, amount of amino acids derived from the peptides and the amount of saccharides, polysaccharides and organic acids in the composition taught by Omori are the same as that claimed by Applicant because

these components are inherent to the composition taught by Omori and claimed by Applicant, absent evidence to the contrary.

Therefore, the reference anticipates the claimed subject matter.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto (O, Translation provided herein).

Yamamoto teaches a seasoning comprising of sesame and barley, which reads on composition, comprising of preparing barley koji and fermenting to provide moromi (which is synonymous with *shochu* stillage), pressing the moromi to provide a clear liquid and then finally filtering the moromi to provide a seasoning (See abstract and paragraphs 0009-0011 and 0018). Yamamoto does not expressly teach an unadsorbed fraction formed by subjecting barley *shochu* stillage to solid-liquid filtration, wherein the unadsorbed fraction contains peptides with an average chain length of 3 to 5 and wherein the peptides comprise 24 to 38% glutamic acid, 4 to 20% glycine, 5 to 10% aspartic acid, 4 to 9% proline and 4 to 8% serine, nor does Yamamoto teach that the total content of amino acids derived from the peptides is from 8 to 14% by weight, nor does Yamamoto teach that the fraction further contains free amino acids, free saccharides, polysaccharides and organic acids nor does Yamamoto teach the fraction contains from 4 to 12% by weight of the free amino acids, from 5 to 10% by weight of the free saccharides, from 15 to 25% by weight of the polysaccharides and from 2 to 8% by weight of the organic acids. However, the composition and fraction, as taught by Yamamoto, is obtained in the same way

and produced in the same manner as the composition and fraction claimed by Applicant and is one and the same as the composition and fraction claimed by Applicant. Therefore, the peptide length, amount of amino acids in the peptides, amount of amino acids derived from the peptides and the amount of saccharides, polysaccharides and organic acids in the composition taught by Yamamoto are the same as that claimed by Applicant because these components are inherent to the composition taught by Yamamoto and claimed by Applicant, absent evidence to the contrary. Please also note that although Yamamoto does not expressly teach a composition having an activity of inhibiting the onset of alcoholic hepatopathy and an activity of healing it, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omori et al. (N, Translation provided herein), in view of Kaneuchi et al. (P, Translation provided herein).

The teachings of Omori are set forth above and applied as before.

Kaneuchi teaches a bowl movement improver, which reads on composition, comprising of a protein fraction derived from beer lees (please note that beer is made from three types of barley and undergoes a fermentation process like shochu production), wherein the beer lees is milled (in a wet state), sieved, further milled, further sieved and dried by freeze-drying or warm air dessication (See abstract and paragraph 0013). Kaneuchi further teaches a protein fraction containing glutamic acid in an amount of between 1 and 40%, wherein a specific example taught by Kaneuchi teaches glutamic acid in an amount of 22.5%. Kaneuchi further teaches glycine in an amount of 3.66%, proline in an amount of 10.64% and serine in an amount of 4.49% (See paragraph 0028). Kaneuchi further teaches the protein fraction from beer lees further contains saccharides (See paragraph 0011). Kaneuchi further teaches that the protein fraction may be used as a drug (See paragraphs 0019-0021).

The teachings of Omori and Kaneuchi are set forth and applied as before. Omori does not expressly teach that the composition comprising of an unadsorbed fraction which is formed by subjecting a barley shochu stillage byproduced in the production of shochu from a barley as a raw material to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbent is a freeze-dried powder, nor does Omori teach a composition used as a drug, nor does Omori teach the synthetic adsorbant is an aromatic synthetic adsorbant or a methacrylic synthetic adsorbant. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been

motivated and had a reasonable expectation of success to modify the composition taught by Omori to provide the instantly claimed invention by freeze-drying the composition comprising of an unadsorbed fraction from barley *shochu* stillage, to use the composition comprising of an unadsorbed fraction from barley *shochu* stillage as a drug and to use an aromatic synthetic adsorbant or a methacrylic synthetic adsorbant because at the time the invention was made it was well known in the art that a protein fraction obtained from alcohol fermentation comprising of a high percentage of glutamic acid and comprising of other amino acids was freeze dried and was used as a drug, as clearly taught by Kaneuchi. Moreover, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the form in which the unadsorbed fraction is obtained and to choose what type of adsorbant to use to effectively filter the composition to obtain the desired purity of product. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

The result-effective adjustment of particular conventional working conditions (e.g., adjusting the type of adsorbant material to use to filter a composition and what form a composition is in) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
Au 1655

Amy L. Clark
May 20, 2006

Michele C. Flood.
MICHELE FLOOD
PRIMARY EXAMINER